



## National Grain and Feed Association

September 30, 1999

Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**Re: Docket No. 99N-1591**

Dear Sirs:

The National Grain and Feed Association submits this statement in response to the regulations proposed by the Food and Drug Administration to implement the Veterinary Feed Directive drugs section of the Animal Drug Availability Act (ADAA)

The NGFA is the U.S.-based nonprofit trade association of about 1,000 grain, feed, processing and grain-related firms comprising 5,000 facilities that handle more than two-thirds of all U.S. grains and oilseeds. The NGFA's membership encompasses all sectors of the industry, including country, terminal and export **elevators**; feed mills; cash grain and feed merchants; end users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity **futures** brokers and commission merchants; and allied industries, such as railroads, barge lines, banks, grain exchanges, insurance companies, computer software firms, and engineering and design/construct companies. The NGFA also consists of 35 **affiliated** state and regional U.S. grain and feed associations, as well as two international **affiliated** associations.

The NGFA strongly supported enactment of the VFD concept as a mechanism for permitting the introduction, as well as prudent dispensation and distribution, of certain animal drugs not classified as over-the-counter without triggering the onerous pharmacy laws of certain states that apply to dispensing of prescription drugs. As FDA notes in the background section of its proposal, "[p]harmacy laws in a significant number of states prohibit feed manufacturers **from** possessing and dispensing prescription animal drugs and medicated feed containing those drugs., , " while still other state laws require the presence of a pharmacist at the feed manufacturing facility that uses prescription drugs in manufacturing medicated feeds. Clearly, as FDA notes, this would be an unworkable situation, something that Congress, too, recognized when passing the VFD provisions of the ADAA.

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However, passage of the VFD section of the **ADAA** places a special responsibility on livestock and poultry producers, the feed industry and – especially – veterinarians to ensure that animal drugs classified by the agency as VFD drugs are prescribed and distributed in a responsible manner that protects human and animal health. This makes it incumbent that VFD-classified drugs be issued only if a valid **veterinarian-client-patient** relationship exists.

The NGFA generally supports FDA's proposed regulations as a framework for achieving this important, overarching objective. In particular, the NGFA wants to articulate its specific support for the following provisions contained in the FDA-proposed rule:

- **Section 514.1(b)(9):** The NGFA strongly supports FDA's proposal to require the submission of a VFD format as part of the new animal drug application for each VFD drug, and to require that VFD drug manufacturers provide veterinarians with preprinted **VFDs** in triplicate. Having a standardized form for each VFD drug will facilitate the transmission of complete VFD information by the veterinarian to the distributor of feeds containing VFD drugs. Later in this statement, the NGFA recommends a modification to Section 558.6 that would ensure that this form is used by veterinarians to convey VFD information to feed distributors.
- **Section 558.3(b)(11):** The NGFA suggests that FDA consider expanding this section to provide that the acknowledgement letter and the notification letter can be combined into a single document so long as it includes **all** information required for both. This would reduce paperwork burdens and provide needed flexibility to feed distributors.
- **Section 558.6(d)(1)(i-iii):** The NGFA supports as reasonable requirements **FDA's** proposal that feed manufacturers and others distributing medicated feeds containing VFD drugs be required to notify the agency only once, by written correspondence, and that the notification include each business site from which such feeds will be distributed.
- **Section 558.6(d)(1)(iv):** The NGFA believes FDA's proposal is reasonable that distributors of medicated feeds containing VFD drugs notify FDA within 30 days of any change in business name or address.

- **Section 558.6(d)(2)(i and ii):** The NGFA supports the concept of utilizing a written acknowledgement letter to be provided to a distributor by a consignee who is not the ultimate user of the medicated feed containing the VFD drug. The NGFA **further** supports the requirement that the consignee obtain an affirmative statement **from** the ultimate distributor that it has complied with the distributor-notification requirements.

The NGFA recommends the following modifications and amplifications to the FDA-proposed rule:

- Amend Section 558.6(a)(3) to require that veterinarians provide all of the information required on the VFD before it is considered to be valid. The NGFA is concerned about reports received from its members concerning the failure of some veterinarians to fill out all of the information required on the VFD form, which places an unreasonable burden on the feed manufacturer. The NGFA recommends that this section of FDA's proposed regulations be strengthened by amending it to read as follows: "(3) You must complete **all of the information required on** the VFD in writing, and sign it: **VFD's that contain incomplete information will be considered invalid.**" [New language boldfaced and underscored.]
- Amend Section 558.6(a)(4) to require that veterinarians use the form provided by the Type A drug manufacturer to convey the required VFD information to feed distributors. This could be accomplished by revising the proposed rule as follows: "(4) You must produce the VFD in triplicate, **using the form provided by the drug: manufacturer.**" [New language boldfaced and underscored]
- Amend Section 558.6(b)(4) to clarify what FDA intends when it uses the term "immediately" to refer to the amount of time the veterinarian has to provide the original, signed VFD order to the feed distributor to follow up on an order transmitted by facsimile. In these situations, the NGFA suggests that the veterinarian be required to deliver the original, signed VFD order within 24 hours.

Further, the NGFA recommends that this section be amended to require that the veterinarian fax the VFD order on company stationery, and that the order be signed.

Further, in response to questions posed by FDA in its rulemaking:

- The NGFA strongly opposes the telephonic transmission of VFD orders **from** a veterinarian to a distributor of VFD feeds. We believe telephonic transmission of VFD orders, even if followed up by a written, signed order from the veterinarian, poses too great a risk of error and could provide opportunities for **fraudulent** communication of **VFD** orders by **non-**veterinarians. It also places an undue burden on the feed manufacturer/distributor of feeds containing VFD drugs to substantiate the authenticity of the VFD information.

Similarly, the NGFA also opposes the transmission of VFD orders by electronic mail, primarily because of the risk that such orders will contain incomplete information. This concern would be alleviated somewhat if a standardized VFD order form (discussed later) is made available to veterinarians in an electronic format.

The NGFA does not necessarily oppose the transmission of VFD orders by facsimile, provided the order: 1) is transmitted on the veterinarian's stationery and is signed by the veterinarian; 2) is followed up by the prompt issuance of the original, written, signed order within 24 hours; and 3) there are sufficient safeguards to minimize the risk of fraudulent transmission of VFD orders by non-veterinarians.

- The NGFA strongly supports the prohibition on the extra-label use of VFD drugs. We suggest that FDA use these criteria when judging whether to approve refills or reorders of VFD drugs, as well as the length of time for which **VFDs** are valid. The NGFA believes it is prudent that FDA take a strong oversight role in these areas.

Finally, the NGFA strongly recommends that FDA include – either in the regulations, or in an accompanying compliance policy guide – a provision stipulating that failure to have a valid veterinarian-client-patient relationship when prescribing VFD drugs, or failure to consistently provide complete VFD information to feed distributors, will constitute a violation of these regulations and will subject the veterinarian to revocation of his/her privilege to issue VFD drug orders. This is consistent with the proposed rule's statement that the veterinarian "assumes the responsibility for safe and effective use of the VFD." It is vitally important to the success of the VFD program that each segment – veterinarian, feed manufacturer/distributor and producer/feeder – assume their separate, distinct – but complementary – responsibilities under these proposed rules, and that the feed manufacturer/ distributor not be placed in the role of being the "policeman" for veterinarians' performance.

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The NGFA also commends FDA's Center for Veterinary Medicine for issuing the agency's first regulations under the "plain English" mandate of the Clinton administration. We believe the format, clarity and preciseness with which the regulations are written will enhance their understanding and facilitate compliance and effective enforcement.

The NGFA appreciates FDA's consideration of its views, and would be pleased to respond to any questions you may have.

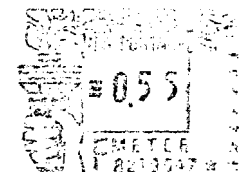
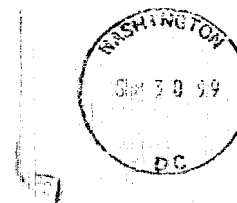
Sincerely yours,

A handwritten signature in black ink, appearing to read "Don Gringer". The signature is fluid and cursive, with the first name "Don" and last name "Gringer" clearly distinguishable.

Donald Gringer  
Chairman  
Feed Industry Committee



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